

WHAT IS CLAIMED IS:

- 1 1. A method for treating hyperplasia or neoplasia in a body lumen,
2 said method comprising:
3 cooling an inner surface of the body lumen to a temperature and for a time
4 sufficient to inhibit subsequent cell growth.
- 1 2. A method as in claim 1, wherein the body lumen is an artery
2 subject to hyperplasia resulting from treatment of a stenosis.
- 1 3. A method as in claim 2, wherein the treatment comprised balloon
2 angioplasty.
- 1 4. A method as in claim 2, wherein the cooling step is performed
2 within one hour following treatment of the stenosis.
- 1 5. A method as in claim 1, wherein the cooling step comprises
2 lowering the temperature of the luminal surface to from 0°C to -80°C for a time period in
3 the range from 1 second to 10 seconds.
- 1 6. A method as in claim 1, wherein the cooling step comprises:
2 introducing a catheter into the body lumen;
3 positioning a balloon on the catheter proximate a target site on the inner
4 surface;
5 expanding a gas within the balloon to cryogenically cool the target site.
- 1 7. A method as in claim 6, wherein the expanding step comprises
2 flowing liquid nitrogen to a Joule-Thomson orifice positioned within the balloon so that
3 the nitrogen expands across the orifice.
- 1 8. A method as in claim 7, wherein the pressure within the balloon is
2 maintained at from 30 psi to 100 psi and the temperature near the orifice is in the range
3 from -40°C to -100°C.
- 1 9. A method as in claim 8, wherein the temperature at each end of the
2 balloon is above 0°C.

1 10. A method as in claim 6, wherein the balloon has a length of at least
2 1 cm and the orifice is positioned at least 0.5 cm from each end.

1 11. A method as in claim 6, wherein the balloon dimensions and the
2 gas expansion conditions are selected to produce a temperature profile over the length of
3 the balloon with a temperature between the ends below 0°C and temperatures at each end
4 above 0°C.

1 12. A method as in claim 1, wherein the cooling step comprises:
2 introducing a catheter body into the body lumen;
3 positioning a balloon on the catheter proximate a target site on the inner
4 surface;
5 vaporizing a liquid within the balloon to cryogenically cool the target site.

1 13. A method as in claim 6, further comprising measuring a
2 temperature of the target site with a thermocouple mounted outside the balloon and
3 controlling the gas expansion based on the measured temperature. *to a clamp*

1 14. A cryosurgical catheter for use in a blood vessel having a vessel
2 wall, the cryosurgical catheter comprising:
3 a flexible catheter body having a proximal end, a distal end, and a lumen
4 defining an axis therebetween;
5 an axially elongate balloon disposed at the distal end of the catheter body
6 in fluid communication with the lumen, the balloon having a balloon wall that can expand
7 radially to engage the surrounding vessel wall;
8 a diffuser head having at least one port in fluid communication with a
9 cooling fluid supply, the diffuser head movable axially within the balloon between a first
10 position and a second position.

Sub A 1
1 15. A method for treating a blood vessel having a vessel wall, the
2 method comprising:
3 introducing a catheter into the blood vessel;
4 expanding a balloon of the catheter near a target site to engage the vessel
5 wall;

6 expanding fluid at a first location within the balloon; and
7 expanding fluid at a second location within the balloon to cryogenically
8 cool at least a portion of the engaged vessel wall, the second location being separated
9 from the first location.

1 16. The method of claim 15, further comprising moving a diffuser head
2 between the first location and the second location.

1 17. The method of claim 16, wherein a housing separates the balloon
2 and the vessel wall when the orifice head is at the first location, wherein fluid expansion
3 is initiated at the first location, and wherein the moving step moves ports of the diffuser
4 head from within the housing after a reduction in thermal transients of the gas expansion.

1 18. The method of claim 15, wherein fluid expansion occurs
2 simultaneously at the first and second locations, the balloon being axially elongate, the
3 first and second locations being separated axially.

1 19. The method of claim 15, wherein the fluid expansion occurs
2 simultaneously at the first and second locations so that the fluid flows radially toward the
3 vessel wall, the first and second locations being separated circumferentially.

1 20. The method of claim 15, wherein the first and second expansion
2 steps comprise vaporization of at least a portion of the fluid from a liquid to a gas so that
3 the enthalpy of vaporization cools the at least a portion of the engaged vessel wall.

1 21. The method of claim 15, wherein the first and second expansion
2 steps are effected by passing the fluid through at least one Joule-Thompson orifice.

1 22. A method for treating a blood vessel having a vessel wall, the
2 method comprising:
3 introducing a catheter into the blood vessel;
4 expanding a balloon of the catheter near a target site within the vessel wall,
5 the balloon having a balloon wall;
6 cooling the vessel wall with the balloon by coating at least a portion of an
7 inner surface of the balloon wall with a liquid so that the liquid coating vaporizes within
8 the balloon.

1 23. A system for treating a blood vessel having a vessel wall, the
2 system comprising:
3 a flexible catheter body having a proximal end and a distal end;
4 an intravascular balloon disposed near the distal end of the catheter body,
5 the balloon expandable to radially engage a surrounding vessel wall, the balloon having
6 an inner surface; and
7 a cooling liquid coating at least a portion of the inner surface of the
8 balloon, the cooling liquid vaporizing within the balloon to cool the vessel wall.